

REMARKS

Reconsideration and withdrawal of the rejections of the claimed invention is respectfully requested in view of the amendments, remarks and enclosures herewith, which place the application in condition for allowance.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 1-6 and 11-20 are pending in this application with the entry of this amendment. New claims 16-20 refer to additional specific embodiments of the invention; all of the claims do NOT encompass the situation where A = oxygen (The Saito reference has an oxygen at the corresponding position of their compound). No new matter has been added.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited in the Office Action, and that these claims were in full compliance with the requirements of 35 U.S.C. § 112. The amendments of the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply for clarification and to round out the scope of protection to which Applicants are entitled.

II. THE 35 U.S.C. 102(b) REJECTION HAS BEEN OVERCOME

Claims 1-6 and 11-15 have been rejected as being anticipated by Saito et al. (EP 0864567 – “Saito”). The applicants request reconsideration for the following reasons.

The applicants are perplexed by the response to the arguments presented by the applicants against the anticipation rejection first made in the non-final rejection.

First, the statement that “chirality is not applicants’ invention and there is no support in the specification to show that this application relates to such an invention” is simply incorrect. The applicants clearly refer to chiral centers at 1, 2 and 1* in their chemical formulas throughout the specification and also use these depictions of chiral centers in their claims and also refer to at least stereochemical purity of from 60 to 100% (R).

Second, the defense of Saito as a valid anticipatory reference in the final rejection is contrary to PTO policy and case law which has been adhered to for almost sixty years. “The existence of a compound as an ingredient of another substance does not negate novelty in a claim to the pure compound, although it may, of course render the claim unpatentable for lack of invention [obviousness].” *In re Williams*, 171 F.2d 319, 320 (CCPA 1948). This rule that lack of novelty will not render an enantiomer unpatentable over its previously disclosed racemate has

been consistently applied. Jonathan J. Darrow, *The Patentability of Enantiomers: Implications for the Pharmaceutical Industry*, Stanford. Tech. L. Rev., 2007, at 3, available at <http://strl.stanford.edu/pdf/darrow-patentability.pdf>.¹ (Footnote 41 also states “The general rule of the Patent and Trademark Office is that, although “[a] genus does not always anticipate a claim to a species within the genus,... when the species is clearly named, the species claim is anticipated no matter how many other species are additionally named.”)

In the present case, the applicants specific enantiomeric species which requires at least 1R is not disclosed by Saito nor is the genus of potential compounds of Saito sufficiently small so as to put into possession by one of ordinary skill in the art the applicants’ claimed compounds.

Therefore, the applicants’ claims are not anticipated by Saito and this rejection should be withdrawn.

II. THE 35 U.S.C. 103(a) REJECTION HAS BEEN OVERCOME

Claims 1-6 and 11-15 have been rejected as being anticipated by Saito et al. (EP 0864567 – “Saito”). In addition to the arguments made above, the applicants maintain their position from their response to the non-final rejection. Although this alone is believed to be sufficient to overcome the obviousness rejection, the applicants have requested a 3-month suspension of action in order to possibly present a declaration which provides further evidence against the holding of obviousness.

CONCLUSION

In view of the remarks and amendments herewith, the application is believed to be in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date, and, the Examiner is invited to telephonically contact the

¹ See also, e.g. *Pfizer Inc. v. Ranbaxy Labs.*, 405 F.Supp.2d 495, 519 (D. Del. 2005)(“[C]ourts considering issues related to racemates and their individual isomers have concluded that a prior art disclosure of a racemate does not anticipate the individual isomers of the racemate....”; *In re May*, 574 F.2d 1082, 1090 (CCPA 1978)(“The novelty of an optical isomer is not negated by the prior art disclosure of its racemate.”); *Brenner v. Ladd*, 247 F.Supp. 51, 56 (D.D.C 1965)(“[I]t should be noted that plaintiff’s [enantiomer] is not considered by this court to be anticipated by the solution of the [racemate] disclosed in the [prior art.]”); *Sterling Drug Inc. v. Watson*, 135 F.Supp. 173, 176 (D.D.C. 1955)(“[I]t matters not that [the enantiomer] in some form in combination may exist in nature, if it cannot be reduced to a form in which it can be used. It is this product which has been so reduced or resolved that it can be used that is here claimed.”)

undersigned to advance prosecution. The Commission is authorized to charge any fee occasioned by this paper, or credit any overpayment of such fees, to Deposit Account No. 50-0320.

Respectfully submitted,
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